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TO: Examiner: Marschel, A.
Group Art Unit 1631
U.S. Patent & Trademark Office
Facsimile No. (703) 872-9306

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Number of pages (including this cover page): 4

In re Patent Application of:)	Group Art Unit: 1631
)	
McDONOUGH <i>et al.</i>)	Examiner: Marschel, A.
)	
Serial No. 08/480,472)	Confirmation No. 9286
)	
Filed: June 6, 1995)	Atty. Docket No. GP034-03.DV1
)	
For: NUCLEIC ACID SEQUENCE AMPLIFICATION)	Date: February 24, 2004
)	

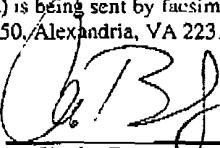
Transmitted herewith is a Request for Reconsideration & Interview Summary.

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence (and any referred to as attached) is being sent by facsimile to 703-872-9306 on the date indicated below to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: February 24, 2004

By:


Charles B. Cappellari
Registration No. 40,937
Attorney for Applicants

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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REQUEST FOR RECONSIDERATION & INTERVIEW SUMMARY

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Examiner's Final Action mailed on December 29, 2003, Applicants respectfully request reconsideration based on the remarks set forth below. These remarks summarize the substance of a telephone interview between Applicants' representative and the Examiner today.

The rejection of claims 39-41, 67-73, 84, 86, 88-90, 92, 98, 150, 158-162, 168, 173, 176, 180-184, 186, 192-194, 197, 198, 204-213 and 222-226 under 35 U.S.C. § 103(a) as being unpatentable over Boddinhaus *et al.* (*J. Clin. Microbiol.* (1990) 28:1751) taken in view of Suzuki *et al.* (*J. Bact.* (1988) 170(6):2886) was maintained by the Examiner. Boddinhaus was cited by the Examiner for "generically suggesting and motivating the preparation of probes and/or primers to distinguish microorganisms via sequence differences," and Suzuki was cited for disclosing sequence differences which "in combination with the . . . Boddinhaus *et al.* motivation and suggestion to make probes and/or primers therefrom results in a series of optional probe and/or primer species." See Final Action at page 3, lines 16-26. Applicants respectfully submit that the Examiner's characterization of the combined teachings of the references is improper because it fails to consider the references in their entirety. See MPEP § 2141.02 at 2100-122 (8th ed., Rev. February 2003).

REQUEST FOR
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Boddninghaus discloses a technique for differentiating between very closely related mycobacterial species based on the amplification and detection of nucleic acid sequences from 16S rRNA. *See* Boddninghaus at p. 1751, col. 2. Boddninghaus stresses the importance of this technique, as there are a number of mycobacterial species, in addition to *M. tuberculosis*, that can cause severe lung disease. *See* Boddninghaus at p. 1751, col. 1. Thus, Boddninghaus teaches the importance of designing primers capable of amplifying regions of nucleic acid that are specific to particular mycobacterial species or to particular members of the genus *Mycobacterium*. Suzuki, on the other hand, illustrates 16S rRNA sequence differences between *M. bovis* BCG, *E. coli* and *S. lividans* but does not provide any motivation for amplifying and detecting any of the particular regions disclosed for *M. bovis* BCG. Thus, one skilled in the art reading Boddninghaus and Suzuki for all that they teach would conclude that the 16S rRNA sequences of additional mycobacterial species would be required before any motivation existed for designing probes and primers to the region of Suzuki identified by the Examiner. *See also* Example 1 of previously cited U.S. Patent No. 5,541,308 (a probe having specificity for *M. tuberculosis* should be capable of distinguishing *M. tuberculosis* over *M. intracellulare*, as these two organisms have an approximately 98% rRNA homology). Any contrary reading of the references would require improper hindsight reconstruction, as the references provide no motivation whatsoever for distinguishing, by any means, between *M. bovis* BCG, *E. coli* and *S. lividans*. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

Applicants submit that the subject application is in condition for allowance and Notice to the effect is respectfully requested.

No fee is believed due in connection with this Request. If Applicants are mistaken, please charge the amount due to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

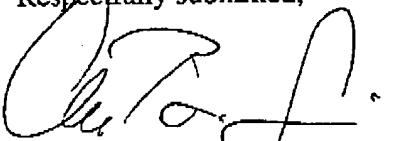
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Respectfully submitted,



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Attorney for Applicants

Dated: February 24, 2004

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